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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,510	06/26/2000	JOHN P. HELGESON	WARF H108	6417

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/463,510

Applicant(s)

HELGESON ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 9 is/are allowed.
- 6) ☒ Claim(s) 1, 4-7 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Status Of The Application

1. This Office action is in response to the Amendment and Remarks filed 10 March 2003.
2. Claim 3 has been cancelled and new claims 16-19 have been added in the instant application.
3. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 1, 5-7 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claims 1 and 17, the sole designation of a marker by a non-art recognized designation is arbitrary and creates ambiguity in the claims. For example, the RAPD or RFLP markers disclosed in this application could be designated by some other arbitrary means, or the assignment of the marker name could be arbitrarily changed to designate another marker. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claims to refer to the sequence identification number that identifies the claimed marker would obviate this rejection. Claims 5-7 are also indefinite because said claims do not obviate the indefiniteness of claim 1.

Applicant argues that, as applied to claim 1, and claim 17 as outlined above, the designation of a marker solely by a name is not indefinite and that one of skill in the art would know the metes and bounds of the claimed invention (pages 8-9 of the Remarks). This argument is not found to be persuasive, for example the CT88 RFLP marker appears to encompass a marker first used for chromosome mapping of *Lycopersicon esculentum* and *Solanum melongena* and Applicant has defined said marker by three different nucleotide sequences, hence the metes and bounds of these limitations remain unclear.

6. Claims 1 and 4-7 remain rejected and claims 16-19 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 6 November 2002. Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive.

Applicant argues that Applicants have disclosed the mapping of one genetic source of late blight resistance in *S. bulbocastanum* to chromosome 8 and have linked it to at least two RAPD markers and five RFLP marker. Applicant further argues that the production of somatic hybrids of *S. tuberosum* and *S. bulbocastanum* and numerous backcross progeny thereof, wherein the presence of late blight resistance is at least 95% correlated with the presence of one or more of the RAPD or RFLP marker is

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described (pages 10-13 of the Remarks). This argument is not found to be persuasive because the RAPD and RFLP markers only describe a chromosomal location, and the Examiner notes that the CT88 RFLP marker describes a chromosomal location of Solanaceous plants other than potato, such as tomato and eggplant. The instant claims are directed to a potato plant only described by phenotype, wherein the structural features of the claimed genus have not been adequately described by which one of skill in the art would have recognized that Applicant was in possession of the invention as broadly claimed.

As directed to claim 7, Applicant argues that claim 7 does not claim that segment (the resistance-conferring segment of *S. bulbocastanum* chromosome 8) as a separate entity (page 12, 1st paragraph of the Remarks). This argument is not found to be persuasive because claim 7 is directed to the gene that confers the resistance to late blight is incorporated into the plant by genetic transformation of a cell, as such Applicant has failed to describe an isolated "gene" that is required to make the claimed potato plant.

7. Claims 1 and 4-7 remain rejected and claims 16-19 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the somatic hybrid potato plants produced by somatic hybridization between *Solanum tuberosum* and *Solanum bulbocastanum* as set forth at Table 3 on page 24 of the specification, does not reasonably provide enablement for any potato plant comprising a segment of chromosome 8 of *Solanum bulbocastanum* which comprises a gene that confers resistance to late blight or a transformed potato plant that is late blight resistant. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 6 November 2002. Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches a late blight-resistant potato plant produced by a combination of somatic hybridization and traditional breeding methods comprising backcrossing and selecting progeny having disease resistance co-segregating with a physical marker. Applicant argues that the specification has met the enablement requirement of teaching a mode of making and using the invention as claimed in claim 1. Applicant also argues that one skilled in the art would also be able to produce the potato plant of claim 1 by recombinant means in view of the recitation and teachings of physical markers associated with the late blight-resistance conferring segment of *S. bulbocastanum* chromosome 8 (page 15, 2nd paragraph of the Remarks). The arguments are not found to be persuasive. As directed to a potato plant comprising the late blight-resistance conferring segment of *S. bulbocastanum* chromosome 8, it is clear from the teachings of the art that transfer of the late blight-resistance conferring segment of *S. bulbocastanum* chromosome 8 into a *S. tuberosum* somatic hybrid is not a predictable art and a wide range of phenotypic variation occurs among such somatic hybrids as outlined in the previous Office action. In addition, as directed to transgenic potato plants comprising the late blight-resistance conferring segment of *S. bulbocastanum* chromosome 8, Applicant has failed to teach how to make and use such

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a potato plant specifically because Applicant does not teach one of skill in the art what "segment" to use or the nucleotide sequence of the late blight-resistance gene to be incorporated.

In addition, Applicant does not teach one of skill in the art how to make and use the potato plant at claims 5 and 19, because there is no teaching in the instant specification that the taught potato somatic hybrids are resistant to potato early blight, *Erwinia* soft rot or *Verticillium* wilt as claimed.

Claim Rejections - 35 USC § 102

8. Claims 1, 4 and 6 remain rejected and claims 16-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Schumman *et al* (1991, *Physiologia Plantarum*, 82: A23, Abstract 134, December) taken with the evidence of Naess *et al* (2000, *Theor. Appl. Genet.* 101:697-704). This rejection is repeated for the reason of record as set forth in the last Office action mailed 6 November 2002. Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive.

Applicant argues that the mere fact that the late blight-resistance in the hybrids disclosed by Naess was traced to *S. bulbocastanum* chromosome 8 does not necessarily mean that the late blight resistance in the hybrids of Schumann was conferred by any portion of *S. bulbocastanum* chromosome 8 (page 17 of the Remarks). This argument is not found to be persuasive. In the instant case the claimed potato plant and that disclosed by Schumman are produced by identical methods and display the same characteristic, that being late blight-resistance. Applicant has provided no evidence that the somatic hybrid potato plant of Schumman does not inherently

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comprise the same feature as that of the instant claimed product. The Office does not have the capacity to determine the difference between the prior art composition and that of the instant claims (See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)). Applicant's argument as directed to the other *Solanum* species is not relevant to the instant rejection because the prior art specifically discloses a somatic hybrid between *S. tuberosum* and *S. bulbocastanum*. Without evidence to the contrary, Applicant appears to disclose an unknown property, which is inherently present in the prior art.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Claims 8 and 9 are allowed.

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11. Claims 1 and 4-7 remain rejected and new claims 16-19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
21 May 2003

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SUPERVISORY PATENT EXAMINER
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